AULISA

Guardian Angel® Rx
Guardian Angel® Rx Lite

Infant Oximeter Module

Instructions For Use

7MN00077-01

Disclaimer

At the time of publication, this manual is believed to be accurate and up-to-date. In the interest of continued product development, Taiwan Aulisa Medical Devices Technologies, Inc. reserves the right to make changes and improvements to this manual and the products described within at any time, without notice or obligation.

References to “Aulisa” in this manual shall imply Taiwan Aulisa Medical Devices Technologies, Inc.

Aulisa is a registered trademark of Taiwan Aulisa Medical Devices Technologies, Inc.

CAUTION!!! Read this entire manual carefully before using Infant Oximeter Module of Aulisa Digital Vital Sign Monitoring System.

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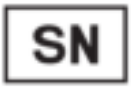
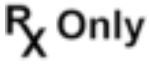
Table of Content

Guide to Symbols

Symbol	Description
	Refer to instruction manual
	MR Unsafe: must not be used in an MRI environment.
	Type BF-Applied Part (patient isolation from electrical shock)
	indicates separate collection for electrical and electronic equipment (WEEE).
	Non-ionizing electromagnetic radiation. Equipment includes RF transmitters. Interference may occur in the vicinity of equipment marked with this symbol.
	Manufacturer
	Serial number
	Lot number
	Non-sterile
	Date of manufacture
	Temperature limit
	Humidity limitation
	Prescription use only

IP23	Classification for water ingress and particulate matter
	Single use
	Do not use if package is damaged

Welcome

This manual will help you get started with monitoring using the Infant Oximeter Module of Aulisa Digital Vital Sign Monitoring System (Guardian Angel® Rx and Guardian Angel® Rx Lite). The Infant Oximeter Module is intended for use with Aulisa Digital Vital Sign Monitoring System. Refer to the system Instructions for Use for detailed instructions.

Precautions for Use

Contraindications

1. Do not use any part of this device in an MRI or CT environment.
2. Explosion Hazard: Do not use this device in an explosive atmosphere or in the presence of flammable anesthetics or gases.
3. This device is not a replaceable for a caregiver.

Warnings

1. This device is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
2. A functional tester cannot be used to assess the accuracy of this device. This device does not require calibration.
3. This device readings may be affected by the use of an electrosurgical unit.
4. Anemia may affect the accuracy of the measurement.
5. As with all medical equipment, carefully route all cables to reduce the possibility of entanglement, strangulation or injury to the patient.
6. Make sure the device is not easily reached by children and pets. Be careful with small parts that can be removed from the device and swallowed.
7. Excessive pressure to the sensor application site for prolonged periods may cause damage to the skin beneath the sensor.
8. Do not use this device if it is damaged in any way. Discontinue using it immediately and replace with a new one.
9. Do not use in or around water or any other liquid when AC power adaptor or the system is used.
10. Only use this device with charging adaptors provided by Aulisa.
11. The Infant Disposable Oximeter Sensor and Adhesive Patch are for single use only.

12. This device is designed to determine functional oxygen saturation, the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin, such as methemoglobin, might affect the accuracy of the measurement.
13. Use this device only when it is within the specified distances, approximately 32.8 feet (10 meters) spherical radius to the Aulisa Digital Vital Sign Monitoring System. Moving outside this range may cause missing, lost, and/or inaccurate data.
14. Loss of monitoring can result if any objects hinder the pulse measurement. Ensure that no blood flow restrictors (e.g., blood pressure cuff) hinder pulse measurements.
15. This device is not a substitution for physical supervision.
16. Always refer to Instructions For Use for full warnings and instructions.
17. Failure to follow instructions and warnings may result in serious injury or death.
18. Nail polish or artificial nail can impact the accuracy of the device.
19. Do not modify the device in any way.
20. Improper use, excessive pressure or drop may lead to malfunction or permanent damage to the device.
21. Verify the compatibility of the accessories before use, or patient may get hurt.
22. Do not use the device on wounds or inflammatory skin. Please immediately remove the device if there is any discomfort or irritation.
23. Only use this device with oximeter sensor provided by Aulisa.

Cautions

1. This device complies with International Standard IEC 60601-1-2: 2014 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of interference due to close proximity or strength of a source might disrupt the device's performance.
2. Radios and cell phones or similar devices can affect the wireless connection of this device and must be kept at least 6.5 feet (2 meters) away from it.
3. If this device fails to respond as described, discontinue use until the situation is corrected by qualified personnel.
4. Cardiogreen and other intravascular dyes may affect the accuracy of SpO_2 measurements.
5. This device might not work on cold extremities due to reduced circulation. Warm or rub the foot to increase circulation or reposition the sensor.
6. This device might misinterpret motion as good pulse quality. Minimize motion of the monitored site.

7. Excessive ambient light may affect the accuracy of the measurement.
8. Inspect and relocate the sensor application site at least every 6 hours to ensure correct sensor alignment and skin integrity. Personal sensitivity to a sensor may vary due to medical status or skin condition.
9. Do not place liquids on top of the device.
10. Do not immerse the device or any of the components in any liquids.
11. Do not use caustic or abrasive cleaning agents on the device.
12. Do not gas sterilize or autoclave this device.
13. Batteries might leak or explode if used or disposed of improperly.
14. Follow local governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
15. Do not subject the device to extreme hot or cold temperatures, humidity, or direct sunlight.
16. Do not fasten this device too tightly around the foot. Inaccurate readings and discomfort could result.
17. System connection failure (Bluetooth connection) may result in loss of data transfer.
18. The device should be set up by adults.
19. The device should be used indoor.
20. Do not use the device when taking a shower.

Device Overview

GA-OM0016	GA-OM0017
	

Device Components

Infant Oximeter Box	Infant Reusable Oximeter Sensor
	
Adhesive Patch	**Infant Disposable Oximeter Sensor**
	
Charging Adaptor	**Leg Band**
	

Device Description

The Infant Oximeter Module is a component of the Aulisa Digital Vital Sign Monitoring System. The Infant Oximeter Module is comprised of the Infant Oximeter Box and a sensor i.e., Infant Reusable Oximeter Sensor or Infant Disposable Oximeter Sensor.
The device is worn on the foot to continuously record SpO_2 and pulse rate of infant patients. The vital sign data gets transmitted to the Aulisa Digital Vital Monitoring System via Bluetooth technology. The data provided by Infant Oximeter Module is intended to aid caregivers in making diagnoses by providing additional information to standard of care patient monitors.

Infant Oximeter Box

The Infant Oximeter Box is secured on the foot by the Aulisa-provided leg band. The Infant Oximeter Box is embedded with a Bluetooth transmitter and a sensor chip along with electronics for vital sign measuring and analyzing. The Infant Oximeter Box must be used within 32.8 feet (10 meters) spherical radius to the Aulisa Digital Vital Monitoring System.

Infant Reusable Oximeter Sensor

The Infant Reusable Oximeter Sensor is intended to be attached to the Infant Oximeter Box on one end and using the Adhesive Patch to wrap around the big toe on the other end. The Adhesive Patch is for single use only. Discard the Adhesive Patch after use. The Adhesive Patch can be purchased separately.

Infant Disposable Oximeter Sensor

The Infant Disposable Oximeter Sensor is intended to connect to the Infant Oximeter Box on

one end and be wrapped around the toe on the other end. It is for single use only. Discard the sensor after use. The sensor can be purchased separately.

Leg band

The reusable leg band is intended to secure the Infant Oximeter Box on the calf.

Device Intended Use

The Aulisa Infant Oximeter Module is intended to measure SpO_2 and pulse rate of infant patients during non-motion and under well-perfused conditions in hospitals, medical facilities, home care, and subacute environments. The parameters derived by Aulisa Infant Oximeter are transmitted to Aulisa Digital Vital Sign Monitoring System for display.

Device Principle of Operation

This device measures SpO_2 and pulse rate based on non-invasive light-emitting diode (LED) reflectance technology, measuring the absorbance of red and infrared light passed through the perfused tissue during each pulse.

Device Set Up

Before you begin your monitoring session, unpack the Infant Oximeter Module and become familiar with its parts. It is recommended to fully charge the battery of the Infant Oximeter Module prior to set up. It takes approximately 2 hours to fully charge. Refer to “Device Charging” section for detailed instructions.

Step 1. Scan the QR code of Infant Oximeter Box with Aulisa Digital Vital Sign Monitoring System.

NOTE: The Infant Oximeter Module is intended to be used with Aulisa Digital Vital Sign Monitoring System. Refer to the system Instructions for Use for set up instructions and verifying system operation.

Step 2: Attach the sensor to the toe.

If you use the **reusable** sensor, follow the instructions below to put on the Infant Oximeter Module.

❶	❷
	
Peel off the arch-shaped section of the release paper of the Adhesive Patch.	Place the back of the sensor probe over the hole in the center of the Adhesive Patch (on the red circle). Ensure it is well attached.
❸	❹
	
Peel off the rest of the release paper.	Place the center of the sensor probe on the bottom center of the big toe. Attach the top of the Adhesive Patch toward the front of the toe.
❺	❻
	
Gently wrap the upper left and right sides of the Adhesive Patch around the big toe.	Gently wrap the lower left and right sides of the Adhesive Patch around the sole.

If you use the ***disposable*** sensors, follow the instructions below to put on the Infant Oximeter Module.

For the **Infant Disposable Oximeter Sensor**, follow the steps below.

❶	❷
	
Peel off the white release paper of the adhesive patch.	Place the center of the sensor probe on the bottom center of the big toe. Attach the top of the Adhesive Patch toward the front of the toe.
❸	❹
	
Gently wrap the sides of the Adhesive Patch around the toe to overlap and secure the sensor probe to the toe.	Press the Adhesive Patch tightly to ensure there are no gaps.

Step 3: Secure the Infant Oximeter Box with the Leg Band.

Thread the Leg Band (loop side facing upward) through the rectangular holes of the Holder.

Step 4: Set up the Infant Oximeter Module.

Plug the Infant Reusable or Disposable Oximeter Sensor into the Infant Oximeter Box.

Step 5: Secure the Infant Oximeter Module around the calf.

Secure the Leg Band around the calf.

Step 6. Press the Power On/Off button to turn on the Infant Oximeter Module.

All done!

NOTE: The Power On/Off LED will light green when the power is ON. The Medium-Priority Alarm LED will light orange when sensor detached from oximeter box.
NOTE: It is recommended to wear socks and to use medical-grade breathable tape to secure the Infant Oximeter Sensor to the foot and enhance the wearing effect.
NOTE: Properly clean the Infant Reusable Oximeter Sensor probe before each use.
NOTE: After use, it is recommended to spray 75% alcohol on the Adhesive Patch to facilitate removal.

Step 7: Connect wirelessly Infant Oximeter Module to the system.

Wait for the wireless connection of the system to be established. Once connected, the vital signs of the Infant Oximeter Module status information will appear on the MAIN screen.

NOTE: Refer to "Device Pairing" section below for more information.
NOTE: The device must be used within 32.8 feet (10 meters) spherical radius to Aulisa Digital Vital Sign Monitoring System.
NOTE: The power LED on the Infant Oximeter Box will blink green when pairing succeeds, and data transmission starts.

Device Pairing

Manual Pairing

Follow the below instructions to manually setup pairing of a new Infant Oximeter Module.

NOTE: Up to two (2) Infant Oximeter Modules can be stored in the system.

Step 1: Turn on the Aulisa Sensor Module(s) and Aulisa Digital Vital Sign Monitoring System.

Step 2: Click on the settings menu in the upper left corner of the MAIN screen.

Step 3: Select "Module Pairing" to enter the pairing page.

Step 4: Point the camera lens at the barcode on the label of Aulisa Sensor Module(s), or click KEY IN in the upper right corner and manually enter the Serial Number on the label to pair the Aulisa Digital Vital Sign Monitoring System with it.

Step 5: When the Bluetooth connection status icon on the MAIN screen turns blue, it means the connection was successful. If the Bluetooth connection is not established automatically, press PAIR button on the MAIN screen to force the system to pair.

NOTE: Make sure the battery is installed and fully charged before use.
NOTE: The device remains paired with the system until the serial number is deleted from the list.
NOTE: The device must be placed within 32.8 feet (10 meters) spherical radius to Aulisa Digital Vital Sign Monitoring System.
NOTE: The Power On/Off LED lights green when the power is ON.
NOTE: The Power On/Off LED will blink green when the data are being transmitted.

Device Power Off and Removal

The device will be turned off by pressing the Power On/Off button on the Infant Oximeter Box.

NOTE: The power LED goes off when power off.

When removing the device, it is recommended to spray 75% alcohol on the probe to facilitate removal.

Device Charging

The Infant Oximeter Module is powered by a rechargeable battery. When the low battery alarm is displayed, the battery is exhausted and needs recharging. Follow the instructions below to recharge the battery.

Step 1: Plug the Type-C end of the charging adaptor into the charging port on the Infant Oximeter Box.

NOTE: **The Infant Oximeter Module works for up to extra 40 minutes in the low power status.**
NOTE: **It takes approximately 2 hours to fully charge the Infant Oximeter Box.**
NOTE: **The charging LED indicator lights blue during charging and goes off when fully charged.**

Step 2: Attach the wall adaptor to a power outlet.

CAUTION!!! **Only use charging adaptor supplied or manufactured by Taiwan Aulisa Medical Devices Technologies, Inc.**

Alarms

The Infant Oximeter Box is equipped with an Alarm LED indicator that will blink red when a high-priority alarm occurs and light orange for medium-priority alarm.
For more information about the alarm, refer to the Instructions for Use of Aulisa Digital Vital Sign Monitoring System.

Care and Maintenance

The advanced digital circuitry within the Infant Oximeter Module requires no calibration or periodic maintenance. Field service or repair of this system is not possible. Do not attempt to open the case of Infant Oximeter Module for that will cause damage and void the warranty. If the Infant Oximeter Module is not functioning properly, see “Troubleshooting” section for more

information.

Cleaning

The Infant Oximeter Module is included in the system kit for use. The Infant Oximeter Module is expected to be cleaned before use, i.e., once per day. It has been tested to withstand 300 times of cleaning within 1.5 years of re-use life. Do not use the Infant Oximeter Module that has exceeded its re-use life.

We recommend you clean the Infant Oximeter Module with the instructions below.

Lightly wipe the surface of the Infant Oximeter Module with a soft cloth dampened with rubbing alcohol for cleaning. Allow the device to dry thoroughly. Visual inspection is necessary at the end of cleaning. Repeat the previous steps to remove visible residual soil on the device. Do not use a visibly soiled device again.

Reuse Life

The Infant Oximeter Box and the Infant Reusable Oximeter Sensor are reusable with an expected life of 1.5 years. However, if you notice any signs of deterioration from below, stop using it and replace it with a new one or contact Aulisa Customer Support by going online at www.aulisa.com:

- button malfunctions;
- cracks appear on external case;
- edge of the gel covering the sensor probe window starts curling up;
- the strap frays or breaks and the wires inside become exposed.

Using deteriorated component(s) may cause the device performance to degrade and do harm to the user.

CAUTION!!! Do not pour or spray any liquids onto this device, and do not allow any liquids to enter any openings in the device.

CAUTION!!! Do not immerse the device in liquid and do not use caustic or abrasive cleaning agents on the device.

Troubleshooting

Problem	Possible Solution
Cannot power on the Infant Oximeter Module	1. Make sure the Infant Oximeter Module is kept away from any magnetic devices while using. 2. Fully charge the Infant Oximeter Module until the LED blue light goes off.
Unable to obtain a valid SpO_2 or pulse rate reading **NOTE: In some instances, perfusion of person being monitored may be inadequate for pulse detection**.	1. Reposition the Infant Oximeter Sensor(s) and keep it motionless for at least 10 seconds. 2. Position the Infant Oximeter Sensor(s) to a different site. 3. Make sure the Infant Oximeter Module is attached to the leg and foot securely. 4. Check the accessories for any visible signs of deterioration. 5. Warm the foot by rubbing or covering with a sock. 6. Allow the foot to rest comfortably without squeezing or pressing the sensor probe on a hard surface. 7. Make sure the Infant Oximeter Module is within 32.8 feet (10 meters) spherical radius to the Aulisa Digital Vital Sign Monitoring System. 8. Reduce or eliminate any interference. Make sure the Infant Oximeter Module is NOT placed on the same leg being used for other medical therapies or diagnostics (e.g., blood pressure cuff). 9. Check the Aulisa Digital Vital Sign Monitoring System for any alarms or error messages. 10. Check if the Infant Oximeter Module is in low power. 11. Verify the system connection with the Aulisa Digital Vital Sign Monitoring System. 12. Make sure that the Infant Oximeter Module is not in proximity with other RF radiating devices (such as diathermy, electrocautery, RFID, and

	security systems).
Unstable or constant SpO_2 and Pulse Rate readings	1. Shield the sensor probe from any light source. 2. Position the Infant Oximeter Sensor(s) to a different site. 3. Make sure the Infant Oximeter Module is attached to the leg and foot securely. 4. Check the sensor probe for any visible signs of deterioration. 5. Reduce motion of person being monitored.
"---" appears on the vital sign displays	1. Make sure the Infant Oximeter Module is attached to the leg and foot securely. 2. Reposition the Infant Oximeter Sensor(s) and keep it motionless for at least 10 seconds. 3. Position the Infant Oximeter Sensor(s) to a different site. 4. Make sure the Infant Oximeter Module is within 32.8 feet (10 meters) spherical radius to the Aulisa Digital Vital Sign Monitoring System. 5. Verify the system connection with the Aulisa Digital Vital Sign Monitoring System.
Data update period has exceeded the limit	1. Reposition the Infant Oximeter Sensor(s) and keep it motionless for at least 10 seconds. 2. Position the Infant Oximeter Sensor(s) to a different site.
Cannot establish system connection	1. Make sure the device is within 32.8 feet (10 meters) to the Aulisa Digital Vital Sign Monitoring System. 2. Power off the Aulisa Digital Vital Sign Monitoring System and retry.

For additional troubleshooting, refer to the system Instructions for Use.

If these solutions do not correct the problem, please contact your distributor, or contact Aulisa by going online at www.aulisa.com under "Contact Us".

CAUTION!!! This system is a precision electronic instrument and must be repaired by knowledgeable and specially trained Aulisa personnel only. Do not attempt to open the case other than the battery cover or repair the electronics.

Device Performance

SpO2 Accuracy

SpO2 accuracy testing is performed by in vivo accuracy testing under laboratory conditions on healthy subjects with varying skin pigmentation in an independent research laboratory through induced hypoxia studies. Analysis of bias* was performed vs. Hemoximeter data. The limits of agreement shown are calculated per: Bland JM, Altman D. (2007) Agreement between methods of measurement with multiple observations per individual. Journal of Biopharmaceutical Statistics 17, 571 – 582.

Root mean square error (RMS error) is calculated as follows:

$$\text{RMS Error} = \sqrt{\frac{\sum (SpO_2 - SaO_2)^2}{n}}$$

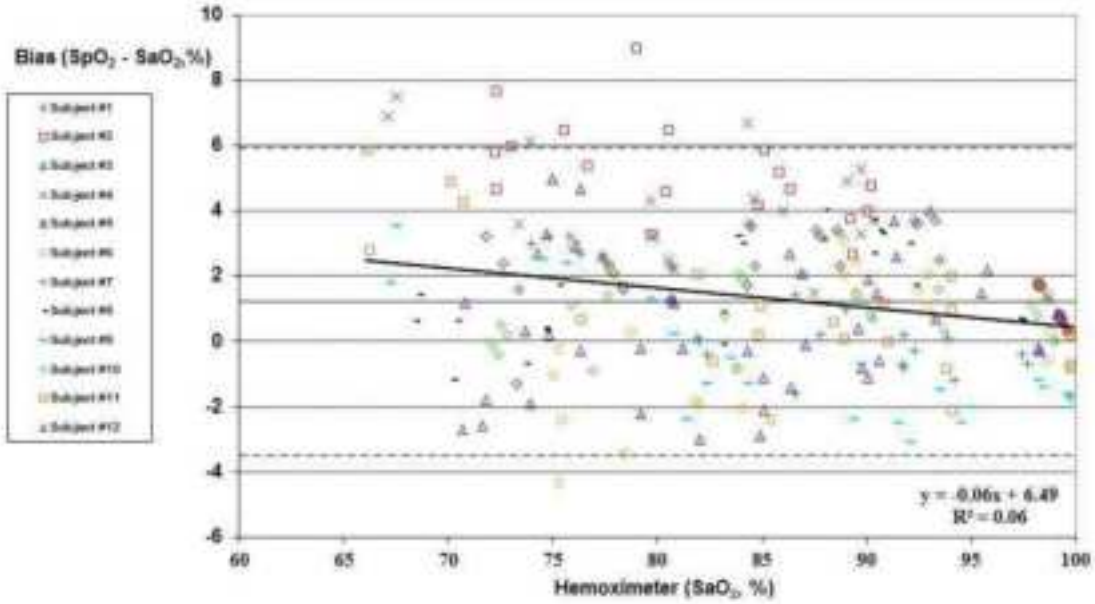
*Bias is defined as the monitor under test reading minus the hemoximeter reading.

NOTE: Because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of this device measurements can be expected to fall within ±Arms of the value measured by a co-oximeter.

A_{rms} from the Clinical Study

Accuracy (A_{rms})	90%-100%	1.82
	80%-90%	2.66
	70%-80%	3.19

The graph below shows the error (SpO_2 – SaO_2) plots of each subject measured by this device with upper and lower 95% limits of agreement. Each sample data point is from a clinical study in healthy volunteers.



Pulse Rate Accuracy

Pulse rate accuracy has been functionally tested against an electronic pulse simulator from 30 to 300 bpm in 10bpm intervals, with combinations of Pulse Amplitude settings of 0.5, 1, 3, 5, 7, 10, 12, 15, 17 and 20, and SpO_2 settings of 100%, 95%, 90%, 85%, 80%, 75% and 70%. All 1960 combinations of testing points (=7 x 28 x 10) of Pulse Rate passed the ± 3 digits acceptance criteria.

Equipment Response Time

This device uses a moving average to determine the pulse rate and SpO_2. The following table shows the equipment response time of this device.

Equipment Delays (second)	
Data Averaging	≤ 4 seconds
Alarm Condition Delay	≤ 4 seconds
Alarm Signal Generation Delay	0 second
Data Update Period	1 second

Manufacturer’s Declaration

Refer to the following table for specific information regarding compliance to IEC 60601-1-2 for this device.

***For all EQUIPMENT and SYSTEMS**

Guidance and Manufacturer's Declaration - Electromagnetic Emission		
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	This device is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker Emissions IEC 61000-3-3	Complies	

***For all EQUIPMENT and SYSTEMS**

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical Fast Transient / Burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Line to Line	±1 kV Line to Line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% UT in 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT in 1 cycle at 0° 70% UT in 25/30 cycles at 0° 0% UT in 250/300 cycles at 0° and 180°	0% UT in 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT in 1 cycle at 0° 70% UT in 25/30 cycles at 0° 0% UT in 250/300 cycles at 0° and 180°	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the AC mains voltage before application of the test level.			

***For EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Conducted RF IEC 61000-4-6	3 V 150 kHz to 80 MHz 6 V ISM and amateur radio bands	3 V 150 kHz to 80 MHz 6 V ISM and amateur radio bands	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]
Radiated RF IEC 61000-4-3	10 V 80MHz to 2.7 GHz	10 V 80MHz to 2.7 GHz	Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b. Over the frequency range 150 kHz to 80 MHz, fieldstrengths should be less than [3] V.

FCC Compliance

Declaration of Conformity with FCC for Electromagnetic Compatibility

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesignated operation.

Federal Communications Commission (FCC) Notice

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy.

If not installed and used in accordance with the instructions, it may cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on. The user is encouraged to try to correct the interference by one or more of the following measures:

(1) Reorient or relocate the receiving antenna.

(2) Increase the separation between the equipment and receiver.

(3) Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

(4) Consult the dealer or an experienced radio/TV technician for help.

The device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on the safety standards previously set by both U.S. and international standards bodies. This equipment has been shown to be capable of compliance for localized specific absorption rate (SAR) for uncontrolled environment/ general population exposure limits specified in ANSI/IEEE Std. C95.1-1992 and has been tested in accordance with the measurement procedures specified in IEEE Std. 1528-200X (Draft 6.5, January 2002).

FCC Radiation Exposure Statement

For body worn operation, to maintain compliance with FCC RF exposure guidelines, use only accessories that contain nonmetallic components. RF exposure separation distance is 5 mm. Use of other accessories may violate FCC RF exposure guidelines and should be avoided.

The FCC requires the user to be notified that any changes or modifications to this device that are not expressly approved by Taiwan Aulisa Medical Devices Technologies, Inc. may void the user's authority to operate the equipment.

CAUTION!!! No modifications to this device are allowed that in any way affect or alter its antenna or antenna configuration.

Service, Support, and Warranty

Taiwan Aulisa Medical Devices Technologies, Inc. (“Aulisa”) warrants to the purchaser that each of Aulisa's product will be free from material defect for a period of one year from the date of purchase (the “Warranty Period”), and Aulisa will repair or replace at its discretion, free of charge, each Aulisa's product found to be materially defective during the Warranty Period and for which Aulisa has been notified during the Warranty Period (the “Warranty”). This Warranty shall be the sole and exclusive remedy by the purchaser for the Aulisa product delivered to the purchaser, irrespective whether such remedy is under contract, tort, or by law.

Aulisa's obligation under the Warranty is only if (i) Aulisa has received written notice of the warranty claim within the Warranty Period, (ii) purchaser has returned the product to Aulisa in accordance with instructions provided on Aulisa's support webpage, and (iii) Aulisa has verified that the product is defective. Aulisa warrants a replacement or repaired product only for products purchased from authorized resellers and only for the unexpired term of the Warranty Period for the defective product.

A return merchandise authorization (“RMA”) and its associated RMA number is required before any product can be returned to Aulisa. To obtain this return authorization number, please contact Aulisa Customer Support by going online at www.aulisa.com under "Contact Us".

Under this Warranty, the purchaser is responsible for the cost of delivery of the product to Aulisa's place of repair as designated by Aulisa, and Aulisa is responsible for the cost of delivery back to the purchaser. Aulisa reserves the right to charge a fee for a warranty repair request on an Aulisa product that is found to be within specifications and without material defect.

Privacy Policy

This Privacy Policy was last updated on March 22, 2019.

Our Policy

This privacy policy applies to personal information collected by Taiwan Aulisa Medical Devices Technologies, Inc. ("Aulisa", "we", "us" and/or "our") from users of the Aulisa remote monitoring devices (the "Devices"). "Personal Information" includes any information that can be used on its own or with other information to identify or contact a single person or to identify an individual in context. If we can link particular information (directly or indirectly) to an individual, we will consider this information "Personal Information," and we will protect it.

WE AT AULISA VALUE KEEPING YOUR PERSONAL INFORMATION CONFIDENTIAL AND USING IT SOLELY IN THE CONTEXT OF OUR MISSION TO PROVIDE CONTINUOUS MONITORING OF VITALS IN ORDER TO AID PEOPLE BEING MONITORED, HEALTHCARE PROVIDERS ("PROVIDERS"), AND CAREGIVERS MAKE INFORMED DECISIONS ABOUT YOUR CARE.

THE PERSONAL INFORMATION WE COLLECT AND TRANSMIT MAY INCLUDE HEALTHCARE INFORMATION, INCLUDING MEDICAL INFORMATION. THEREFORE, OUR PRIVACY PRACTICES ARE INTENDED TO COMPLY WITH THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT ("HIPAA"). WE WILL MAINTAIN THE PRIVACY OF YOUR HEALTH INFORMATION AS REQUIRED BY HIPAA AND THE REGULATIONS PROMULGATED UNDER THAT ACT. FOR ADDITIONAL INFORMATION RELATED TO YOUR HEALTHCARE INFORMATION, PLEASE CONTACT information@aulisa.com.

We believe that transparency about the use of your personal information is important. In this privacy policy, we provide you detailed information about our collection, use, maintenance, and disclosure of your personal information. The policy explains what kind of information we collect, when and how we might use that information, how we protect the information, and your rights regarding your personal information.

Please read the following carefully to understand our views and practices regarding your Personal Information and how we will treat it. For the purposes of Applicable Data Protection Laws including the European Economic Area data protection law (the "Data Protection Law"):

Non-Provider Users: The data controllers are the Provider and Taiwan Aulisa Medical Devices Technologies, Inc., No. 218-2, Chong Yang Rd., Nangang Dist., 11573 Taipei City, Taiwan

Provider Users: The data controller is Taiwan Aulisa Medical Devices Technologies, Inc., No. 218-

2, Chong Yang Rd., Nangang Dist., 11573 Taipei City, Taiwan

Data Protection Officer: Augustine Lien

BY USING THE DEVICES, YOU ARE ACKNOWLEDGING THAT YOU HAVE READ AND AGREE TO THE TERMS OF THIS PRIVACY POLICY. IF YOU DO NOT AGREE, PLEASE DO NOT USE THE DEVICES AND DO NOT SUBMIT ANY INFORMATION TO US.

Access to and use of the Devices by a Provider who is an Aulisa customer (a "Customer") and such Customer's authorized users is subject to and governed by the agreement between Aulisa and the applicable Customer executed by authorized representatives of each party (the "Customer Agreement"). Aulisa may collect, use and disclose information from a Customer and such Customer's authorized users as set forth in the Customer Agreement. If you would like more information about the Devices or becoming a Customer, please contact us at information@aulisa.com.

Changes

PLEASE NOTE THAT WE OCCASIONALLY UPDATE THIS PRIVACY POLICY AND THAT IT IS YOUR RESPONSIBILITY TO STAY UP TO DATE WITH ANY AMENDED VERSIONS. IF WE MODIFY THIS PRIVACY POLICY, WE WILL NOTIFY YOU OF THE CHANGES ON OUR WEBSITE, AN IN-SERVICE NOTICE OR OTHER REASONABLE MEANS. YOU CAN STORE THIS POLICY AND/OR ANY AMENDED VERSION(S) DIGITALLY, PRINT IT, OR SAVE IT IN ANY OTHER WAY. ANY CHANGES TO THIS PRIVACY POLICY WILL BE EFFECTIVE IMMEDIATELY UPON POSTING, AND SHALL APPLY TO ALL INFORMATION WE MAINTAIN, USE AND DISCLOSE. IF YOU CONTINUE TO USE THE DEVICES FOLLOWING SUCH NOTICE, YOU ARE AGREEING TO THOSE CHANGES.

Capitalized terms, if not defined in this Privacy Policy, are defined in the documentation that came with your Devices.

❖ *What Information Do We Collect and Why?*

Personal Data that You Provide Through the Devices

We collect Personal Information (e.g. demographic information) from you when you voluntarily provide such information to us, use the Devices (including without limitation, the software featured on the Devices and/or platforms), contact us with inquiries, or use certain features of the Devices. We use this information to allow the Devices to provide the information to you and/or your Provider.

In addition to demographic information, if you are a person being monitored, we collect Health Data through the Devices. Such Health Data may include information about your vital signs, health conditions, age, gender, weight, and height. We collect this information to communicate

information to your healthcare provider.

Primarily, the collection of your Personal Information assists us in providing a means to track your vital signs in order to better enable you to communicate information with caregivers and healthcare providers and be an active participant with those providers in monitoring your care, tailoring interventions, and assessing treatment outcomes. We may also use your Personal Information to (1) store data; (2) comply with the law; (3) respond to requests from public and government authorities; (4) to enforce our terms and conditions; (5) manage and improve our operations and applications; (6) provide additional functionality; (7) protect our rights, privacy, safety or property, and/or that of yours or others; and (8) allow us to pursue available remedies or limit the damages we may sustain.

Failure to Provide Information

Providing your Personal Information is not statutorily or contractually mandated. If you choose not to provide this information, we cannot monitor your vital signs, and you will be unable to use our Devices.

Support Information

If you contact Aulisa for support or to lodge a complaint, we may collect technical or other information from you. Such information will be used for the purposes of troubleshooting, customer support, software updates, and improvement of the Devices in accordance with this Privacy Policy. Calls with Aulisa may be recorded or monitored for training, quality assurance, customer service, and reference purposes.

Aggregated Personal Data: In an ongoing effort to better understand and serve our customers, other users of the Devices, and communities of people with similar health conditions, Aulisa may conduct research on its user demographics and behavior based on the Personal Information we collect from you and the other information provided to us. This research may be compiled and analyzed on an aggregate basis, and Aulisa may share this research and related information in aggregated, de-identified and/or anonymized format with its affiliates, agents and other healthcare research and services entities, including without limitation insurance and pharmaceutical companies. For the avoidance of doubt, this aggregate information does not identify you personally. Aulisa may also disclose aggregated, de-identified and/or anonymized information in order to describe our business and the Devices to current and prospective business partners and Customers, and to other third parties for other lawful purposes.

❖ *Where Is My Personal Information Stored And/Or Processed?*

Information Aulisa collects through the Devices will be processed and/or stored on secure third-party cloud-based servers or through a Wi-Fi network. All of the information you share with us through the Devices is double-encrypted during transmission using AES-128 data encryption as

well as an Aulisa private encryption method.

❖ *Will You Share My Personal Information With Anyone Else?*

We consider your information to be a vital part of our relationship with you. There are, however, certain circumstances in which we may share your Personal Information with certain third parties without further notice to you. Those circumstances are described below:

With Our Provider Customers: If you are a person being monitored, we will share your Personal Information and Health Data with our Provider Customer(s) that provide healthcare services to you. This will enable your Provider to track your Health Data and combine such Health Data with other information about you that your Provider obtains in providing healthcare services to you.

With Caregivers: If you are a person being monitored, family and/or friends may view certain of your Personal Information and/or Health Data and related alerts.

In the Event of a Business Transfer: We might sell or buy businesses or assets. In the event of a corporate sale, merger, reorganization, dissolution or similar event, Personal Information may be part of the transferred assets.

With Related Companies: We may also share Personal Information with Aulisa Related Companies for purposes consistent with this Privacy Policy.

With Our Agents, Consultants and Related Third Parties: Aulisa, like many businesses, sometimes hires other companies to perform certain business-related functions. Examples of such functions include data hosting and billing management. When we employ another entity to perform a function of this nature, we only provide the entity with the information that it needs to perform its specific function.

To Meet Our Legal Requirements: We may disclose your Personal Information if required to do so by law or if we have a good faith belief that such action is necessary to (i) comply with a legal obligation, (ii) protect and defend our rights or property, (iii) act in urgent circumstances to protect the personal safety of you, us, other users of the Devices or the public, or (iv) protect against legal liability.

NOTE: **We may, from time to time, rent or sell aggregated data and/or other information that does not contain any personal identifiers (i.e., if the information has been anonymized by stripping out identifiers such as name, address, phone number, etc.). The purpose of this type of disclosure is to allow research institutions to learn more about symptoms associated with your medical condition(s).**

❖ *How Long Will You Retain the Information?*

We only store certain of your Personal Information for as long as you use the Devices and up to five (5) years after you cease to use the Devices. At the end of this five-year period, we will remove your Personal Information from our databases and will request that our business partners remove your Personal Information from their databases. However, once we disclose your Personal Information to third parties, we may not be able to access that Personal Information any longer and cannot force the deletion or modification of any such information by the parties to whom we have made those disclosures. Written requests for deletion of Personal Information other than as described should be directed to information@aulisa.com. We retain anonymized data indefinitely.

❖ *How Do You Protect My Personal Information?*

Aulisa is committed to protecting the security and confidentiality of Personal Information. We use a combination of reasonable physical, technical, and administrative security controls to maintain the security and integrity of your Personal Information, to protect against any anticipated threats or hazards to the security or integrity of such information, and to protect against unauthorized access to or use of such information in our possession or control that could result in substantial harm or inconvenience to you. However, Internet data transmissions, whether wired or wireless, cannot be guaranteed to be 100% secure. As a result, we cannot guarantee the security of information you transmit to us. By using the Devices, you are assuming this risk.

Safeguards

The information Aulisa collects and stores on secure servers is protected by a combination of technical, administrative, and physical security safeguards, such as authentication, encryption, backups, and access controls. If Aulisa learns of a security concern, we may attempt to notify you and provide information on protective steps, if available, through the e-mail address that you have provided to us or other reasonable notification. Depending on where you live, you may have a legal right to receive such notices in writing.

NOTWITHSTANDING ANY OF THE STEPS WE TAKE, IT IS NOT POSSIBLE TO GUARANTEE THE SECURITY OR INTEGRITY OF DATA TRANSMITTED OVER THE INTERNET. THERE IS NO GUARANTEE THAT YOUR INFORMATION WILL NOT BE ACCESSED, DISCLOSED, ALTERED, OR DESTROYED BY BREACH OF ANY OF OUR PHYSICAL, TECHNICAL, OR ADMINISTRATIVE SAFEGUARDS. THEREFORE, WE DO NOT AND CANNOT ENSURE OR WARRANT THE SECURITY OR INTEGRITY OF ANY INFORMATION YOU TRANSMIT TO US AND YOU TRANSMIT SUCH INFORMATION AT YOUR OWN RISK.

❖ *How Can I Protect My Personal Information?*

We will NEVER send you an e-mail requesting confidential information such as account numbers, or social security numbers, and you should NEVER respond to any e-mail requesting such information. If you receive such an e-mail purportedly from Aulisa, DO NOT RESPOND to the e-mail and DO NOT CLICK on any links and/or open any attachments in the e-mail, and notify Aulisa support at information@aulisa.com.

You are responsible for taking reasonable precautions to safeguard the Device from exposure to unauthorized third parties, and you are not permitted to circumvent the use of required encryption technologies.

EU DATA SUBJECT RIGHTS

If you are an EU data subject, you have the following rights under certain circumstances:

- to receive communications related to the processing of your personal data that are concise, transparent, intelligible and easily accessible;
- to be provided with a copy of your personal data held by us;
- to request the rectification or erasure of your personal data held by us without undue delay;
- to request that we restrict the processing of your personal data (while we verify or investigate your concerns with this information, for example);
- to object to the further processing of your personal data, including the right to object to marketing;
- to request that your personal data be moved to a third party;
- to receive your personal data in a structured, commonly used and machine-readable format;
- to lodge a complaint with a supervisory authority.

Where our processing of your Personal Information is based on consent, you have the right to withdraw that consent without detriment at any time by contacting us at information@aulisa.com.

You can also exercise the rights listed above at any time by contacting us at information@aulisa.com.

❖ *How Can I Update, Correct Or Delete My Personal Information?*

If you need to make changes or corrections to your information, you may make such changes or corrections on the Device.

❖ *Information Submission By Minors*

If the Device is being utilized by a minor, and the Devices are being used to monitor a minor, you

represent, warrant and covenant that by agreeing to the terms of this Privacy Policy, you have the legal authority to accept this Privacy Policy on behalf of such minor as the minor's parent or legal guardian. If you do not have such legal authority, do NOT accept this Privacy Policy and do not use the Devices on behalf of such minor.

❖ *How Can I Contact Aulisa?*

If you have any questions or comments about this Privacy Policy, our practices, or our Devices, please feel free to e-mail us at information@aulisa.com.

Specifications

Dimensions	1.87” x 1.82” x 0.63” (47.5mm x 46.2mm x 15.9mm)
Weight	12 g
Ingress Protection	IP23
Display range	
Blood Oxygen Saturation (SpO_2)	1% to 100%
Pulse Rate	30 to 290 bpm
Accuracy	
Blood Oxygen Saturation (SpO_2)	70% to 100% ±3 digits
Pulse Rate	±3% digits
Update Response Time	Every second
Measurement Wavelengths and Output Power	
Red	660 nanometers
Infrared	905 nanometers
Battery Type	3.7V
Battery Life	6 hours of continuous operation
Temperature	
Operating	+5°C to +40°C
Storage/Transportation	-25°C to +70°C
Humidity	
Operating	15% to 90% R.H. non-condensing
Storage/Transportation	10% to 93% R.H. non-condensing
Operating Altitude	altitude ≤ 3000 m
Atmospheric Pressure	700 hPa to 1013 hPa
Wireless Communication	
Frequency	2402-2480 MHz
Protocol	BLE 5.2
Antenna Info	Chip, 2.5dBi

Security	AES-128
Range	32.8 feet (10 meters) spherical radius
Direction	Bi-direction
Data rate	Up to 1M Bps
Classifications per IEC 60601- 1	
Type of Protection	MOPP Class II (on AC power) Internally powered (on battery power)
Type of Protection	Type BF-Applied Part
Mode of Operation	Continuous
FCC ID	2AI5QOB0006

Parts and Accessories

Parts and Accessories	Model Number
Infant Oximeter Box	GA-OB0006
Infant Reusable Oximeter Sensor	GA-RS0010
Infant Disposable Oximeter Sensor	GA-DS0007
Adhesive Patch	GA-AP0013
Leg Band	GA-LB0002
Charging Adaptor	GA-AD0001

For more information about the Aulisa Digital Vital Sign Monitoring System, refer to the system Instructions for Use.

You may also contact your distributor or contact Aulisa by going online at www.aulisa.com under "Contact Us".

CAUTION!!! Using accessories not by Taiwan Aulisa Medical Devices Technologies, Inc. may result in inaccurate measurements. Always use parts and accessories by Taiwan Aulisa Medical Devices Technologies, Inc.